K062489

AUG 15 2007

510(K) SUMMARY

Apex HCLA™ Acetabular Cup Liners — July 12, 2007

1. **Submitter:** OMNI life science™, Inc.
175 Paramount Drive
Raynham, MA 02767

Contact: Edward Cheal, Ph.D.
(508) 824-2444 x413 (voice)
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2. Device Name

Proprietary Name:	Apex HCLA™ Acetabular Cup Liners
Common Name:	Acetabular cup, uncemented
Classification Names:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis; and Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class:	Class II per 21 CFR §888.3353 and 21 CFR §888.3358

3. Intended Use

The Apex HCLA Acetabular Cup Liners are intended for use with the Apex Modular™ Acetabular Cup, in combination with the Apex Modular, Apex K2™, or Apex K1™ Hip Stem in total hip replacement procedures. The acetabular cup liners are intended to articulate with a metal (cobalt chromium) or ceramic (alumina) femoral head. This prosthesis is intended for single use implantation, and may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed;
- Femoral neck and trochanteric fractures of the proximal femur.

4. Device Description

The Apex HCLA™ Acetabular Cup Liners are manufactured of compression molded, cross-linked and stabilized ultrahigh molecular weight polyethylene, sterilized using ethylene oxide. The articular geometry of the liners are compatible with existing Apex Modular femoral heads, manufactured from cobalt chrome or alumina ceramic, 28 mm diameter, with various offsets.

5. Predicate Device Comparison

Substantial equivalence[1] is claimed to the DePuy Marathon™ Cross-Linked Polyethylene Acetabular Cup Liners (K994415, K010171, and K033273). The following table summarizes the similarities and differences between the subject Apex HCLA™ Acetabular Cup Liners and the predicate DePuy Marathon™ Acetabular Cup Liners:

	Apex HCLA™ Liners	Apex Modular UHMWPE Liners	DePuy Marathon™
INTENDED USE			
Modular liner in metal shell, primary and revision total hip replacement	Yes, cementless	Yes, cementless	Yes, cemented and cementless
DESIGN			
Liner engagement	19° taper and PE locking ring	19° taper and PE locking ring	Metal wire locking ring (Duraloc shells) or taper and PE locking ring (Pinnacle® shells)
Minimum UHMWPE thickness (within 45° of apex)*	12.0 mm	6.0 mm	6.0 mm
Liner options	Neutral and 10° hooded	Neutral, 10° and 15° hooded	Neutral and lateralized (neutral and face changing)
Head diameters	28 mm	28 and 32 mm	28, 32, 36 mm
MATERIALS			
Cross-linked UHMWPE	Yes	No	Yes
Sterilization	Ethylene oxide	Ethylene oxide	Gas plasma

*Minimum thickness values for Apex HCLA and Apex Modular liners account for manufacturing tolerances; minimum thickness for DePuy Marathon liners is based on published product literature.

The Apex Modular HCLA Acetabular Cup Liners described in this submission are substantially equivalent to the predicate devices based on similarities in design, intended use, material and manufacturing methods. The locking mechanism is similar to that used in the predicate DePuy Pinnacle liners, and identical to the locking mechanism in the Apex Modular UHMWPE liners (K031110). While the UHMWPE in the Apex Modular liners was not crosslinked, the cross-linked UHMWPE of the subject device is generally similar to the crosslinked UHMWPE of the predicate DePuy Marathon™ liners.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2007

OMNI life science Inc.
c/o Edward J. Cheal, Ph.D.
Vice President of Research
175 Paramount Drive, Suite 302
Raynham, Massachusetts 02767

Re: K062489
Trade/Device Name: Apex HCLA Acetabular Cup Liners
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, MEH
Dated: July 12, 2007
Received: July 13, 2007

Dear Dr. Cheal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062489

Device Name: Apex HCLA™ Acetabular Cup Liners

Indications For Use:

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- Femoral neck and trochanteric fractures of the proximal femur.

Prescription Use__X____ AND/OR Over-The-Counter Use_____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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